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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/056,072	04/07/98	BAZIN	H 61750221

EXAMINER

HM12/0413

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GAMBEL, P | PAPER NUMBER 9

1644
DATE MAILED: 04/13/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 1/4/99

☑ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 30-44 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 30-44 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☑ Notice of Reference Cited, PTO-892
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1998-404-496/40517

DETAILED ACTION

1. Applicant's amendment, filed 1/4/99 (Paper No. 6), is acknowledged.
Claim 44 has been added.

Claims 1-29 have been canceled previously.
Claims 30-43 are pending and being acted upon.

2. A substitute specification is required because the numerous entries to be amended in the specification, filed 1/4/99 (Paper No. 6). The substitute specification filed must be accompanied by a statement that it contains no new matter. Such statement must be a verified statement if made by a person not registered to practice before the Office.

3. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Office Action will be in response to applicant's arguments, filed 1/4/99 (Paper No. 6).
The rejections of record can be found in the previous Office Action (Paper No. 4).

4. Again, applicant is required to comply with sequence rules as indicated in the previous Office Action (Paper No. 4) and reiterated herein.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821-1.825, however, this application fails to comply with the requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

The following procedure is to be used for cases that contain the same sequence disclosure as the parent. The applicant need not submit a new computer readable from of the Sequence Listing in this divisional. However, (1) the specification must contain a paper copy of the Sequence Listing, (2) applicant must request in writing that the CRF in the parent case be used to prepare a file for the offspring and (3) applicant must submit a statement that the paper copy of the Sequence Listing in the offspring is identical to the computer readable form submitted in the parent case.

5. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84.
Please see the form PTO-948 previously sent in Paper No. 4.

6. It is apparent that the LO-CD2a antibody/hybridoma is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody (claims 30-44). See 37 CFR 1.801-1.809.

Applicant's arguments including the amendment to the specification, filed 1/4/99 (Paper No. 6), is acknowledged.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Applicant has not provided the appropriate statement.

However, given that the deposit requirements for the LO-CD2a antibody/hybridoma produced by the cell line deposited as ATCC HB 11423 have been satisfied and claimed in U.S. Patent No. 5,730,979; the requirement for the LO-CD2a antibody/hybridoma in this application is not necessary.

7. Claims 34 and 42 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34 and 42 are indefinite in the recitation of "chimeric" because the metes and bounds is unclear. For example, chimeric can refer simply to variable (e.g murine) region - constant region (e.g. human) constructs, while humanized would refer to CDR-grafted antibodies. Chimeric antibodies can be a broad term that encompass any number of recombinant forms of antibodies. To clearly define the metes and bounds of said chimeric antibody, applicant is invited to amend the claims to recite that chimeric antibodies refer to variable (e.g murine) region - constant region (e.g. human) constructs. This would distinguish said "chimeric" antibodies from other recombinant forms as well as the other recited form of "humanized" antibodies, which are also chimeric, but refer to CDR-grafted antibodies.

The amendments must be supported by the specification so as not to add any new matter.

Applicant's arguments, filed 1/4/99 (Paper No. 6), have been fully considered but are not found convincing essentially for the reasons of record. Applicant asserts that "chimeric" may include a variety of antibodies, which is well known to those skilled in the art. However, applicant has not set forth or provided the metes and bounds of "chimeric"; nor has applicant distinctly claimed chimeric antibodies to distinguish them from humanized antibodies, which is also claimed. Applicant's arguments are not found persuasive and the rejection is maintained for the reasons of record.

8. Claims 30-32, 35-40 and 43 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Xia et al. (Rat Hybridomas and Rat Monoclonal Antibodies, 1990) for the reasons of record set forth in Paper No. 4).

Claims 30-43 stand rejected under 35 U.S.C. § 103 as being unpatentable over Xia et al. (Rat Hybridomas and Rat Monoclonal Antibodies, 1990) in view of Queen et al. (U.S. Patent No. 5,530,101) or Newman et al. (U.S. Patent No. 5,658,570) and in further view of Guckel et al. (J. Exp. Med., 1991) OR Bromberg et al. (Transplant., 1991) OR Hafler et al. (J. Immunol., 1988) OR Chavin et al. (Transplant., 1992) OR Faustman (U.S. Patent No. 5,283,058).

Applicant's arguments, in conjunction with the Bierer declaration under 37 C.F.R. § 1.132, filed 1/4/99 (Paper Nos. 6/7), have been fully considered but are not found convincing.

Applicant argues in conjunction with the Bierer declaration that during the prosecution of parent application USSN 08/472,281 that one skilled in the art could not produce the deposited antibody that, in turn, one skilled in the art would not be enabled by Xia to produce an antibody which binds to the same epitope. Applicant argues that the characteristics which are defined in Xia are not characteristics which define a specific epitope, but rather address characteristics common to CD2 antibodies as a class. Applicant argues that Xia does not identify the epitope which LO-CD2a antibody binds and does not provide the LO-CD2 antibody; it does not enable the claimed specificity.
Applicant also argues that the prior art is not enabled to treat humans.

In contrast to applicant's arguments, Xia et al. teach the LO-CD2a-specificity and rely upon a number of characteristics to distinguish this specificity, including distinguishing the LO-CD2 specificity from other CD2-specific antibodies. While the characteristics disclose by the prior art may be common to certain classes of CD2-specific antibodies, this reference clearly distinguishes the LO-CD2 antibody specificity from other CD2-specific antibodies, including providing a number of characteristics and comparisons that would lead to an expectation of success of antibodies that bind the same epitope as the LO-CD2a antibody. While applicant/Bierer rely upon certain characteristics disclosed by Xia are encompassed by different antibodies which bind to different epitopes, there is sufficient guidance and direction in the reference to distinguish the LO-CD2a antibody specificity. While applicant relies upon amounts of the claimed antibodies to induce antigen specific hyporesponsiveness, applicant relies upon the intended use of the claimed antibodies. The intended use or amount to elicit alloantigen specific hyporesponsiveness would have been met by the reference as such claimed amounts encompass a broad range as the amount of antibody to elicit said immunosuppression would depend on the nature of the system being analyzed or tested. Further, applicant's reliance on unexpected results do not overcome clear and convincing evidence of obviousness.

It would have prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to generate CD2-specific antibodies including the LO-CD2-specific antibodies to characterize the CD2 specificity and to target said specificity for various biological, diagnostic and therapeutic modalities. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments are not found persuasive.

9. USSN 08/477,989 was not available to the examiner at this time; therefore it is not clear whether USSN 08/477,989 still has antibody compound/composition claims therein. Therefore, the following is reiterated.

Applicant's amendment, filed 1/4/99 (Paper No. 6), did not provide any response to the double patenting rejection of record.

Claims 30-43 and newly added claim 44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-26 of copending application Serial No. 08/477,989. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to same or similar LO-CD2-specific antibodies, including chimeric and humanized antibodies.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 30-43 are directed to an invention not patentably distinct from claims 11-26 of copending application Serial No. 08/477,989. Specifically, the conflicting claims are patentably distinct from each other because both applications are drawn to same or similar chimeric and humanized LO-CD2-specific antibodies, including chimeric and humanized antibodies.

Commonly assigned 08/477,989, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. § 103 if the commonly assigned case qualifies as prior art under 35 U.S.C. § 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37

C.F.R. § 1.78© to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application. A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. § 103 based upon the commonly assigned case as a reference under 35 U.S.C. § 102(f) or (g).

10. Claims 30-43 and newly added claim 44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 18-19 U.S. Patent No. 5,730,979. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to same or similar LO-CD2-specific antibodies/hybridomas/methods of producing antibodies from said cells, including chimeric and humanized antibodies. The patented claims are a species of the instant generic claims 30-43. Newly added claim 44 is a composition comprising the antibody LO-CD2a of U.S. Patent No. 5,730,979. Also, U.S. Patent No. 5,730,979 has been cited above to enable the claimed LO-CD2a antibody/hybridoma.

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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April 12, 1999
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